

REMARKS

Claims 1-11 remain pending in this application. Claim 2 has been amended to delete reference to "forming a step part."

Interview Summary:

Applicants acknowledge, with appreciation, the opportunity to conduct a personal interview with Examiner Ali and her supervisor, Justine Yu, on July 2, 2007. During the interview, each of the prior art rejections were discussed pointing out, as more fully discussed below, why the Sladek patent neither anticipates nor renders obvious any claim in this application. It was pointed out that the Sladek device works on a fundamentally different principle than the claimed invention in that it requires two separate actions by the user: (1) actuation of the canister containing medication particles (col. 2, lines 27-30) and (2) inhalation by the user. In the present invention, on the other hand, inhalation by the user both creates the force necessary to pulverize a pharmaceutical composition into fine particles and inhalation of those particles by the user.

It was also pointed out that Yamashita et al. would be removed as a reference by the following actions: (1) as a § 102(a) publication, Yamashita et al. is being removed by filing an English language translation of the priority document filed 13 December 2002 in Japan; and (2) as a § 102(e) reference applied in a § 103 rejection, it is being removed under the common ownership provisions of § 103(c).

Amendments to the drawings, specification and claim 4 were also discussed to address the objections raised in the Office action. Subject to further consideration of the remarks below and the evidence to remove Yamashita et al. as a reference, the

examiners indicated the claims would receive favorable consideration over the prior art of record.

§ 102(b) Rejection - Sladek (USP 6,039,042):

Claims 10 and 11 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Sladek. As noted above, the Sladek inhalation device is both structurally and functionally different than the claimed invention. The Sladek device requires two separate steps to operate: (1) actuation of the canister that already contains medication particles (col. 2, lines 27-30), and (2) inhalation by the user. The claimed device operates by simple inhalation of the user that draws outside air into the inhalation flow path from an air inlet port that operates to pulverize a pharmaceutical composition into fine particles. The device of Sladek further does not permit the flow of outside air into the inhalation flow path that is recited to be formed by “the inner side space of the main body, the mouthpiece and the vessel.” (Claim 10).

Claim 11 is further distinguished from the device of Sladek by the recited “auxiliary flow path for feeding the outside air into the inhalation flow path” that passes “into the mouth of the user without passing through the orifice” of the divider. The Office has pointed to element (20A) in Fig. 2A of Sladek as constituting the auxiliary flow path of claim 11. However, element (20A) cannot correspond to the recited auxiliary flow path because Sladek describes it as a “one-way exhalation valve.” (Col. 2, line 35). Rather than permitting outside air to be inhaled by the user through element (20A), this element actually blocks the passage of air until the user of the device exhales. Accordingly, Sladek neither teaches nor suggests the devices of claims 10 or 11, and the anticipation rejection should be withdrawn.

§ 103 Rejection - Sladek (USP 6,039,042):

Claims 1-7 have been rejected under 35 U.S.C. § 103(a) as being obvious from Sladek. This rejection is traversed for the same reasons discussed above with respect to the rejection based on anticipation. Claims 1, 2 and 5, and claims dependent thereon (3, 4, 6 and 7) require an inlet flow path to introduce outside air to the chamber to apply the air-generated impact to the pharmaceutical composition. Sladek is not configured to introduce outside air to the pharmaceutical composition. Claims 1 and 4-7 are further distinguished from the device taught by Sladek by the recited auxiliary flow path for directly inhaling outside air. As the teachings of Sladek do not establish a prima facie case of obviousness, this rejection should be withdrawn.

§ 103 Rejection: Sladek and Yamashita et al.

Claims 8 and 9 have been rejected under 35 U.S.C. § 103 as being obvious over Sladek in view of Yamashita et al. (US2003/0101995 A1). Yamashita should not be considered a publication under § 102(a) because applicants have filed concurrently with this reply an English language translation of the priority document having a filing date of 13 December 2002. Since the present claims are supported by the disclosure in the priority document, applicants have established a date of invention prior to the publication date (05 June 2003) of Yamashita et al. Accordingly, Yamashita et al. should be withdrawn as a § 102(a) publication. MPEP 201.15.

Yamashita et al. should be withdrawn as a § 102(e) reference used in a § 103 rejection because the inventions described in Yamashita et al. and the present application were owned by or subject to assignment to the same party (Otsuka) at the time they were made. 35 U.S.C. § 103(c) and MPEP 706.02(I)(1). Accordingly, not only

because of the deficiencies of Sladek discussed above, but also because Yamashita is not available prior art under § 103, this rejection should be withdrawn.

Drawings:

The drawings have been objected to as allegedly failing to illustrate features of the invention specified in the claims. Specifically, the Office has identified the feature of a “suction port” recited in claim 1. This feature is illustrated as element 1a in amended Fig. 3. In addition, the specification at page 15, line 17, has been amended to make reference to element 1a.

The Office also has identified the feature of a “step part” recited in claim 2. This feature can be seen as being the configuration of divider 13 in Fig. 10 where the dimensions of the flow path are reduced in stepwise fashion. However, claim 2 has been amended to delete the reference to “step part” and avoid this objection.

Finally, the Office has objected to the feature of a “plurality of dividers” recited in claim 3. This feature is also illustrated in Fig. 10 by dividers 13 and 131, and described in the specification at page 20, line 22 to page 21, line 1 and page 22, line 24 to page 23, line 5, for example. Accordingly, this objection should be withdrawn.

Specification:

The specification was objected to as failing to use reference numeral 11 consistently throughout the disclosure. The specification has been reviewed and the only instance of an inconsistency that was pointed out by the Office at page 15, line 6, has been corrected. Accordingly, this objection should be withdrawn.

Claim Objection:

Claim 4 was objected to as the Office correctly noted that claims 2 and 3, on which claim 4 depends, already contain a reference to mouthpiece. Accordingly, claim 4 has been amended as suggested by the Office to avoid this objection.

Prompt and favorable reconsideration of this application is requested.

If there is any fee due in connection with the filing of this Reply, please charge the fee to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: July 20, 2007

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Attachments:

English Language Translation
Verification of Translation
Replacement Sheet (3/22)